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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATTEN, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,410	PARADISE, LOU	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-20* is/are pending in the application.

4a) Of the above claim(s) *15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-14 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-2, 5-20 are pending in the application.

It is pointed out that the most recent Amendment does not list pending claim 20 which was added by Applicant in Amendment B, recorded June 12, 2003. Upon a submission of a response, Applicant is asked to correct this error. It is further pointed out that the Examiner made an inadvertent error in the previous Office Action; it was submitted that claims 1-2, 5-14 and 18-20 were pending in the application. However, claims 15-17 were omitted, these claims being withdrawn from the merits as being directed toward a non-elected invention in the response submitted 6/10/03. Therefore, it is hereby clarified that claims 1-2 and 5-20 are pending in the application, while claims 15-17 were withdrawn from consideration and claims 3 and 4 are cancelled.

Claims 1-2, 5-14 and 18-20 were examined on the merits.

Claim Rejections - 35 USC § 112

Claims 1-2, 5-14 and 18-20 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 5-9, 12-14 and 18-20 all recite the term 'disease' without specifying exactly what disease the claim is referring to. Specifically, the claims recite 'wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities…'. It is unclear what diseases Applicant is referring to besides diabetic neuropathy. Further, because of the ambiguity with regard to the recitation in claim 10 which limits the 'disease' to fibromyalgia (please see *infra*), it is further not understood what the intended scope of the term 'disease' in the Instant claims. What other diseases are these claims referring to? Clarification is necessary.

Applicant's arguments were fully considered, but not found persuasive.

It is reiterated that the recitation of the term 'disease' in the claims is broad, but also indefinite. Claim 1 states 'a method for treatment of a disease in the limbs of a patient wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities'. Here, the metes and bounds of the term 'disease' is not clearly delineated because, for example, a person suffering from asthma may incur a leg injury. Therefore, the structure of the claim indicates that this disease, asthma, will be treated with the composition present in the Instant method claims. Thus, it is not absolutely clear what boundaries Applicant intends for the term 'disease' to encompass.

Further, Applicant states " '…a disease in which there is a restriction of blood flow and a reduction in motor and sensory nerve conduction velocities' is generic to

'fibromyalgia' and 'diabetic neuropathy'". However, as indicated in the previous Office action, there is no evidence that fibromyalgia is characterized by such symptoms and Applicant has not provided sufficient evidence to substantiate this contention.

Claims 1-2, 5-14 and 18-20 either recite, or depend upon a claim which recites 'an effective amount'. The metes and bounds of this phrase are not delineated, in that it cannot be ascertained what an 'effective amount' is. Applicant has not provided any indication what an effective amount of the composition would be. Because none of the ingredients listed in the claims were known in the art for treating any of the claimed disorders, the ordinary artisan cannot rely on the state of the art to provide this information. A mere disclosure of a percentage of a constituent in a composition is not considered an 'effective amount'; i.e., the claims state 'About 0.5 to 5% by weight of a vasodilator derived from a plant'. This is deemed to read on 0.5% of a picogram. Is this an effective amount? Lacking a definition in the Specification, the ordinary artisan could not be sure. Thus, the phrase is vague and indefinite, and the ordinary artisan would have trouble determining what Applicant mean by 'effective amount'.

Applicant's arguments were considered, but not found convincing.

Applicant argues that the term 'effective amount' has been further defined (p. 2-Remarks). However, there has been no amendment to the claims which more clearly defines this term. Applicant contends that the term 'has been used in other

homeopathic patents, namely, patent no.5162037...' (p.2- Remarks). Although this term is well known in the art, the Examiner has assessed this term to determine if one of ordinary skill in the art would be able to ascertain what Applicant intends for the term 'effective amount' to mean (i.e., would one of ordinary skill in the art **know if they were in possession** of this aspect of the claimed invention). It is the opinion of the Examiner that the ordinary artisan could not determine an 'effective amount' of each of the claimed constituents; 1) because none of the claimed agents were known for the intended purpose 2) there is no indication in the Specification which even suggests an effective amount and 3) the prior art offers evidence that the amount of at least one of the constituents in the claim is critical; Naja, poisonous snake venom. Additionally, the claim states 'Crotalus horridus'. Is the effective amount of *C.horridus* the whole snake or part of the snake? For these reasons, this term remains indefinite because the ordinary artisan could not determine, based upon the claims or the specification, if they were in possession of an 'effective amount' of any of the constituents in the claims. Correction is necessary.

Claims 1-2, 5-14 and 18-20 remain rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the ad to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments were fully considered, but not found persuasive.

Applicant first argues that the specification teaches how to make the compositions as indicated in the method claims and that no undue experimentation would be required in order to topically administer the composition (pp. 3-4, Remarks).

The Examiner respectfully disagrees for the following reasons: First, to reiterate, an artisan would not understand what an 'effective amount' of any of the constituents are, therefore, the skilled artisan would need to 'make and test' the compositions to ascertain what an effective amount is since it is not disclosed in the Instant specification. Secondly, how would one topically apply *Crotalus horridus*, a venomous snake? It is noted again that the claims do not state *Crotalus horridus* venom or extract, but the snake itself. A complete search of the patented and non-patented literature indicates that snakes are not a typical part of topical compositions. Therefore, it is deemed that the skilled artisan would have a difficult time trying to ascertain how to incorporate a snake into a pharmaceutical preparation lacking sufficient guidance in the Instant specification as well as lack of knowledge thereof in the art.

Applicant states, "The examiner is mistaken in the belief that blood flow restriction is a result of inflammation. Commonly, blood flow restriction is due to trauma where the capillaries become constricted." (p. 3, Remarks). The Examiner concedes, the term 'inflammation' in the previous Office action should have read 'vasoconstriction'

and was an inadvertent error. Applicant goes on to state that " The article in the Merck Manual cites trauma as a cause of fibromyalgia. Stress exacerbates the disease and is not a cause of the disease as indicated by the examiner". It is noted that the Examiner only stated that a treatment of fibromyalgia is stress management as indicated by the Merck Manual. The Examiner is not absolutely clear what point Applicant is intending to make with this statement. However, again, Applicant has categorized 'fibromyalgia' as being a disease which is characterized by 'restriction of blood flow and a reduction in motor and sensory nerve conduction velocities'. There is no evidence, neither in the Instant specification nor the prior art that fibromyalgia is a disease characterized by these parameters (please also see rejection, supra, under 35 USC 112 second paragraph for the recitation of 'disease' in the claims). Nevertheless, as indicated in the previous Office Action, Applicant has not provided any indication that the methods will actually work for fibromyalgia, as no data substantiating such efficacy has been presented.

The Applicant argues that "The Examiner cannot reach an allegation that the compositions will not work based on that which is known in the art" (p.3, Remarks). The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches ***exactly*** how to make or use the invention. The more that is known in the prior

art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (emphasis added, MPEP § 2164.03). It is noted that the basis for the rejection under this statute was not based solely on the unpredictability of each constituent in the composition as was found in the prior art, but it was also based upon the insufficient evidence found in the Instant specification. The specification does not provide any examples where any type of fibromyalgia or diabetic retinopathy were treated (please note that the claims were examined on the merits for these diseases because it is not known what other diseases the claims encompass- see rejections under 35 USC 112 Second paragraph *supra*, as well as in the previous Office Action).

"The present invention is a surprising discovery as evidenced by commercial success" (p.3, Remarks). This statement is not convincing. Although Applicant has provided, as Appendices to the Amendment and response, letters from clients who indicate some beneficial results after use of 'Topricin', **this evidence is not commensurate in scope with the claimed invention**. It is not known what 'Topricin' is, how it is made, or what it contains. Therefore, these letters do not satisfy the requirements under this statute.

Applicant argues that "...patent nos. 5162037 and 4684522...relate to homeopathic preparation and incorporate "snake venom" and "snake gall". These components as well as applicant's are found in Homeopathic Pharmacopedia of the United States" (p.5-Remarks). These patents are not commensurate in scope with the *claimed invention*. The claimed invention specifically teaches Naja, a specific venomous snake poison, as well as **a snake,** *Crotalus horridus*. Predictability with regard to these constituents pertaining to a method for treating diabetic retinopathy and/or fibromyalgia is not found in these patents and therefore their respective disclosures do not remedy the lack of guidance found in the Instant specification.

Applicant argues that the failure of Arnica for treating carpal tunnel as reported in the British Medical Journal (BMJ) as cited by the Examiner was expected; 'how much of the drug would reach the diseased area is a question' (referring to the oral administration of Arnica for treating carpal tunnel syndrome). This reference was cited by the Examiner to indicate that there is questionability in the art with regard to the efficacy of Arnica as a whole. Again, it is pointed out that Arnica is not known in the prior art for treating diseases related to fibromyalgia or diabetic retinopathy, nor has any clear nexus been established which would indicate that Arnica performs some mechanism which would benefit these diseases. Applicant further questions the amount of Arnica which was actually bioavailable in the orally administered Arnica composition disclosed by BMJ. However, it is also not known how much Arnica will be bioavailable as a topical medication as disclosed in the Instant specification and the

Instant claims. It is noted that diabetic retinopathy is a complication of diabetes and a leading cause of blindness. It occurs when diabetes damages the blood vessels in the retina, the tissue at the back of the eye. There is no indication in the specification that the topical compositions have been admixed with any specific transdermal delivery agents that would necessarily penetrate the skin and enter the bloodstream and actually travel to the site of disease (the retina) in order to provide any relief from diabetic retinopathy. In the case of fibromyalgia, because the origins of this disease is unknown, and because the disease is typically characterized by aches and pains, the only viable data which could indicate actual efficacy would be *in-vivo*, in a patient who could clearly relay results; i.e., a human patient, as no acceptable animal models for fibromyalgia have been found in the prior art. However, no such evidence has been provided in the Instant specification.

Applicant states that 'there are three components which work synergistically to produce the desired effect where a desired response is required. The response which is involved is to increase blood flow and to simultaneously improve motor and sensory nerve conduction velocity which according to the dictionary or literal meaning is a condition that impairs normal function' (p.4-Remarks). As indicated in the previous Office action, the claims were searched on the merits with regard to a method for treating diabetic retinopathy and fibromyalgia respectively. It is not known what other diseases Applicant intends to encompass by the recitation of 'motor and sensory nerve conduction velocity'. First, synergism, which is predicated on an unexpected result, is a

highly unpredictable, rare phenomenon. Applicant has not provided data which indicates that the methods actually work in treating diabetic retinopathy or fibromyalgia. Applicant further has not provided any evidence that the combination of elements will provide any efficacious results with regard to any increase in blood flow to improve a 'motor and sensory nerve conduction velocity', nor has Applicant presented evidence that any of the constituents combine to provide for a synergistic result. Thus, argument of synergism appears speculative lacking any substantial evidence of such.

It is again reiterated that the Instant specification provides no working examples, prophetic or real, which demonstrate the composition of the Instant specification will perform as intended by the claims. The Appendices provided by the Applicant also do not clearly show that what is stated in the Instant claims will actually work. This lack of guidance coupled with the unpredictability in the art precludes the skilled artisan from performing the Instantly claimed methods.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A Patten

Examiner
Art Unit 1654

03/29/04

PATRICIA PATTEN
PATENT EXAMINER